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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,494	10/29/2003	Jeffrey M. Sieracki	1023-226US01	5736

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EXAMINER	
ROBERTS, DARIN	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,494	SIERACKI ET AL.	
	Examiner	Art Unit	
	Darin R. Roberts	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,15,17-27,32,34-41 and 47* is/are rejected.

7)☒ Claim(s) *11-14,16,28-31,33,42-46 and 48* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/19/04; 4/12/04* and 3/30/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The Information Disclosure statements dated 3/30/06 and 4/12/04 have been considered

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 15, 17-26, 32, 34, & 35, are rejected under 35 U.S.C. 102(b) as being anticipated by North et al. (US 2001/0007950 A1).

In reference to ***claim 1 & 17***, the North publication teaches the use of an implantable neurostimulator that is capable of being programmed whilst within the body of the user (see abstract). The North et al. publication teaches that a patient interactive computer may communicate with a remote computer server through a telephone line, to obtain value added services or software updates (see pp. [0032]). North also teaches the use of a rating screen found on a controller/programmer device that allows the user to rate the level of relief from the pain by electrostimulation (see pp. [0168] & pp. [0170]). The computer of the North et al. patent also teaches The data may be re-

analyzed or used as the basis for further patient testing on other patient interactive computers, or it may be simply stored in a common data base for the center. Patient data and implant information can be transferred to remote data servers (see pp. [0067]). The north patent also teaches the use of the internet for the network (see pp. [0098])

In reference to ***claim 2***, the North et al. patent teaches a device that is capable of sending signals to a server via a programming device. Such signal can be stimulation parameters and inherently can be sent by a clinicians as well as a patient (see column pp. [0067], pp. [0067], pp. [0218] & pp. [0219]).

In reference to ***claim 3***, North teaches a system wherein the server randomly orders the programs and directs the programming device to control the implantable neurostimulator to deliver neurostimulation according to the random ordering of the programs (see pp. [0204]).

In reference to ***claims 4 & 22***, the North et al. patent teach the use of a numeric rating system that is entered into the user interface (see pp. [0153]).

In reference to ***claims 5, 7 & 15***, the North Patent teaches the use of a patient interactive computer wherein a patient can indicate the area of perceived pain (see pp. [0021]) and thus the area that requires paresthesia. Such information is capable of being transmitted to a server by the patient (see pp. [0037] & pp. [0066]) via the controller mechanism capable of being used by both the clinician and the patient. The North et al. patent also teaches that the control device compares previous data from the area of paresthesia for certain stimulation parameters to the indicated area of pain to determine the amount of overlap for each set of stimulation parameters and in turn

provide the appropriate amount of stimulation. The North et al. device is also capable of presenting the amount of overlap to the patient or clinician (see pp. [0032]). North et al. also teaches the use of a touch screen in conjunction with the device (see pp. [0145]).

In reference to ***claim 6***, the North et al. device possesses a display and displays body outlines, which can be referred to as templates. The North et al device also displays a patient's response to the selected treatment, and responses are displayed and drawn on the same screen as the patient interface (see pp. [0022] & pp. [0023]). The North et al. device teaches the use of a server that is capable of receiving information from the programming device via telephone lines and remote computer server connection capabilities allowing comparison between centers and tracking of implants usage (see pp. [0218], pp. [0219], pp. [0306]).

In reference to ***claim 8***, the North et al. patent teaches the use of a data base where in a server is employed where the server receives selections capable of being made by a clinician of one of the programs via a programming device (see pp. [0037]). North et al. also teaches a device capable of storing stimulating parameters associated with rating information with in a database (see pp. [0066], & pp. [0098]).

In reference to ***claim 18***, the North et al. patent teaches the use of a programmer capable of being held in an individual's hand (see figs. 2 & 3).

In reference to ***claims 19, 20, 25, 26, 32 & 34***, the North et al. patent teaches directing a programming device via a network to control an implantable neurostimulator to deliver neurostimulation according to a plurality of programs during a programming session (see pp. [0098]). North also teaches the use of a rating screen found on a

controller/programmer device that allows the user to rate the level of relief from the pain by electrostimulation (see pp. [0168] & pp. [0170]). The North et al. device is also capable of presenting the amount of overlap to the patient or clinician. North et al. teaches the use of an implantable neurostimulator implanted within a patient receiving rating information for each of the programs via the programming device and the network (see pp. [0032]). The method of rating information for each of the delivered programs found in the North et al. publication is inherently related to the efficacy of that program, and the North et al. device is capable of presenting the rating information to a clinician via the network and the programming device to assist the clinician in selection of one or more of the programs for long-term programming of the implantable neurostimulator (see pps. [0034]-0037]). North et al. also teaches the use of a data memory unit which can be seen as a computer readable medium the is capable of storing instructions (see pp. [0040])

In reference to ***claim 21***, The method of claim 19, further comprising randomly ordering the programs, wherein directing the programming device comprises directing the programming device to control the implantable neurostimulator to deliver neurostimulation according to the random ordering of the programs (see pps. [0204]-[0208]).

In reference to ***claim 23***, The North et al. patent receiving rating information by receiving input from at least one of the patient and the clinician via the programming device and the network indicating an area of pain perceived by the patient (see pp. [0033]), receiving an input from the patient via the programming device and the network

for each of the programs that indicates an area of paresthesia experienced by the patient during delivery of neurostimulation according to the respective program(see pp. [0032] & pp. [0033]). North et al also teaches comparing the area of paresthesia for each of the programs to the area of pain to determine an amount of overlap for each of the programs, and wherein presenting the rating information comprises presenting the amounts of overlap for each of the programs to the clinician (see pp. [0032]).

In reference to ***claim 24***, the North et al patent teaches the use of a body templates displayed after delivery of neurostimulation according to a respective one of the prompts, the body templates illustrating an external surface of a human body (see. pp. [0032]) wherein receiving inputs indicating an area of pain and areas of paresthesia comprises receiving information from the programming device via the network that describes regions of the body templates identified by at least one of the patient and the clinician, and wherein comparing the areas to determine an amount of overlap comprises comparing regions see pp. [0067]).

In reference to ***claim 35***, the North et al. publication teaches a computer-readable further comprising instructions that cause a programmable processor to receive parameters for each of the programs from the clinician via the programming device and the network, the parameters for each of the programs defining neurostimulation delivered according to that program (see pp. [0040]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 9 & 36-41 & 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over North et al. (US 20010007950 B2)

In reference to ***claim 36***, the North et al. publication teaches the use of instructions that cause a programmable processor to randomly order the programs, wherein the instructions that cause a programmable processor to direct the programming device comprise instructions that cause a programmable processor to direct the programming device to control the implantable neurostimulator to deliver neurostimulation according to the random ordering of the programs (see pp. [0204]-[0208]).

North et al. publication does not teach the of computer-readable possessing the aforementioned instructions, however it would have been obvious to one of ordinary skill in the art to place said instructions onto a computer readable medium to allow for instruction to be exchanged between multiple devices.

In reference to ***claim 37***, the North et al. patent teaches instructions that cause a programmable processor to receive rating information comprise instructions that cause a programmable processor to receive a numerical score for each of the programs, the numerical scores entered into the programming device by at least one of the patient and the clinician (pps. [0033], [0153], & [0154]).

North et al. publication does not teach the of computer-readable possessing the aforementioned instructions, however it would have been obvious to one of ordinary skill in the art to place said instructions onto a computer readable medium to allow for instruction to be exchanged between multiple devices.

In reference to ***claim 38***, the North et al. publication teaches the use of instructions that cause a programmable processor to receive rating information comprise instructions that cause a programmable processor to receive input from at least one of the patient and the clinician via a programming device and the network indicating an area of pain perceived by the patient (see pps. [0032], & [0058]-[0061]). North et al. also teaches receiving an input from at least one of the patient and the clinician via the programming device and the network for each of the programs that indicates an area of paresthesia experienced by the patient during delivery of neurostimulation according to the respective program (see (pps. [0033], [0153], &

[0154]) and comparing the area of paresthesia for each of the programs to the area of pain to determine an amount of overlap for each of the programs, and wherein the instructions that cause a programmable processor to present the rating information comprise instructions that cause a programmable processor to present the amounts of overlap for each of the programs to the clinician (see pps. [0032], [0058]-[0061], & pp. [0168]).

North et al. publication does not teach the of computer-readable possessing the aforementioned instructions, however it would have been obvious to one of ordinary skill in the art to place said instructions onto a computer readable medium to allow for instruction to be exchanged between multiple devices.

In reference to ***claim 39***, The computer-readable medium of claim 38, wherein the programming device displays a first body template and additional body templates, that are displayed after delivery of neurostimulation according to a respective one of the programs, the body templates illustrating an external surface of a human body, wherein the instructions that cause a programmable processor to receive inputs indicating an area of pain and areas of paresthesia comprise instructions that cause a programmable processor to receive information from the programming device via the network that describes regions of the body templates identified by at least one of the patient and the clinician (see pps. [0032], [0058]-[0061], & pp. [0168]). The North et al. publication also teaches the use instructions that cause a programmable processor to compare the areas to determine an amount of overlap comprise instructions that cause a programmable processor to compare regions (see pps. [0058]-[0061], & pp. [0168]).

North et al. publication does not teach the of computer-readable possessing the aforementioned instructions, however it would have been obvious to one of ordinary skill in the art to place said instructions onto a computer readable medium to allow for instruction to be exchanged between multiple devices.

In reference to ***claim 40***, The North et al. publication teaches the use of instructions that cause a programmable processor to receive a selection capable of being made by the clinician of one of the programs via the programming device and the network (see pp. [0110] & figs. 3, 5, & 6). North et al also teaches storing the selected program and associated rating information within a database as part of a record for the patient (see pp. [0067] & [0217]-[0219]).

North et al. publication does not teach the of computer-readable possessing the aforementioned instructions, however it would have been obvious to one of ordinary skill in the art to place said instructions onto a computer readable medium to allow for instruction to be exchanged between multiple devices.

In reference to ***claim 9 & 41***, the North et al. publication teaches a device wherein the clinician is capable of selecting a set of stimulation parameters for long-term programming of the implantable neurostimulator (see pps.[0036] & [0064]), and a device comprising instructions that cause a programmable processor to direct the programming device to program the implantable neurostimulator with the selected program (see pps. [0045] & [0104]).

North et al. publication does not teach the of computer-readable possessing the aforementioned instructions, however it would have been obvious to one of ordinary skill

in the art to place said instructions onto a computer readable medium to allow for instruction to be exchanged between multiple devices.

In reference to ***claim 47***, the North et al publication teaches the use of a programming device is a programmer capable of being used by a clinician, as well as instructions that cause a programmable processor to receive rating information from a patient programmer via the network; and store the rating information within the database as part of the record (see pps. [0039]-[0041], [0067] & [0218]).

North et al. publication does not teach the of computer-readable possessing the aforementioned instructions, however it would have been obvious to one of ordinary skill in the art to place said instructions onto a computer readable medium to allow for instruction to be exchanged between multiple devices.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over North et al. (US 6654642 B2) in view of Krichen et al. (US 6250309 B1).

In reference to ***claim 10***, North et al. does not teach storing the symptoms, gender, age, weight, or height of a user. However north does teach the use of a server that receives patient information and device configuration information via the programming device and stores the patient information and device configuration information within the database (see colum8, lead lines 1-16 & column 9, lead lines 49-61). The external transmitter and implanted receiver are RF coupled by an antenna. The North et al. patent teaches the use of an external transmitter that can be worn

externally by the patient to encode the stimulation parameters and the electrode selections, which are then transmitted to an implanted receiver via an antenna. The implant decodes the transmitted information and generates the desired electrical pulses for stimulating electrodes within the spinal column (see column 2, lead lines 14-21)

The Krichen et al. patent teaches the use of an implantable device capable of recording a patient's information including at least one of symptoms, age, height, weight, and sex, and the device configuration information including at least one of a device type, a number of leads, a number of electrodes, a configuration of electrodes and positions of electrodes.

Because an individual's symptoms, gender, age, weight, or height can determining the stimulation parameters it would have been obvious to one of ordinary skill in the art to store an individual's symptoms, gender, age, weight, or height to provide optimal stimulation.

Allowable Subject Matter

Claims 11-14, 16, 28-31, 33, 42-46, & 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The examiner was unable to locate prior art explicitly stating that the server receives a query from the civilian via a programming device.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Boveja et al. (US 2005/0131439 A1) was cited due to its teaching of the use of a server in conjunction with a neurostimulator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571)272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Darin Roberts
Patent Examiner
Art Unit 3762

DR